

### **Remarks**

Claims 1-9, 11-14 and 26-31 are pending in the application.

The Final Office Action mailed August 20, 2008, indicates that claims 1-14 and 26-31 are pending; however, claim 10 was previously cancelled.

With this Submission, claim 1 is amended and claims 32 through 34 are added.

Claims 1-9, 11-14, and 26-34 remain in the application for consideration.

Support for the added claims can be found in the specification as originally filed, for example as follows:

Support for new claim 32 can be found, e.g., at original claims 1 and 3 and at the original figures, including original figures 4, 5, and others and their related text.

Support for new claims 33 and 34 can be found as with claim 32, and also at original claim 4.

Reconsideration and allowance of the claims in light of the following remarks are respectfully requested.

This Submission is being filed with a Request for Continuing Examination.

### **Fees for Additional Claims**

After the present amendments, the claims include two additional claims in excess of twenty and one additional independent claim in excess of three. Enclosed herewith is a check that includes the fee of \$324.00 for additional claims.

### **Arguments for Patentability**

The outstanding rejections of the pending claims are traversed for reasons of record and as follows.

As bases for the rejection, the Advisory Action relies on the following assessments of the claims in view of the Orban reference:

*Orban discloses the tissue approximating structures 110 may be extended (Figure 8) and retracted (Figure 7) from or away from the catheter body wall by moving the catheter 180 proximally or distally. It is not recited that the tissue approximating structures be extended and retracted through the catheter body sidewall. (Emphasis mine.)*

And:

*The claims only require that the tissue approximating structure be extended and retracted from a catheter body wall . . .*

Regarding the first assertion, even if correct, the pending claims distinguish from the Orban reference by other expressly recited features.

Regarding the second assertion, the claims in fact do require more than just structure that can be reextended and retracted from a catheter body wall. The claims also require, e.g., that tissue approximating structure be located proximal to a balloon or an drainage aperture, which prevents the Examiner's proposed comparison to Orban figures 7 and 8.

Certain claims specify that tissue approximating structure is on a proximal side of a drainage aperture or an inflatable balloon. Independent claim 1, for example, as presently amended for clarification, recites:

*tissue approximating structure that can be extended and retracted from the catheter body wall at the distal end of the catheter body on a proximal side of the inflatable balloon*

This language (while not expressly reciting that structures extend through a body sidewall), still acts to distinguish claim 1 from the structure of Orban. Orban does not extend a structure from a catheter body wall on a proximal side of an inflatable balloon. To the contrary, the Orban structure is incapable of extending its described structure from a body wall on a proximal side of any relevant structure. The Orban structure is extended out of an aperture at a distal end of a hollow insertion device. That location is not proximal to any structure, or to any potential structure, of the Orban insertion device. This distinguishes claim 1 from any structure that may be taught or suggested by the Orban reference. As previously presented, the Orban reference does not teach or suggest extending a fastener structure from an insertion device at any location other than by expelling the structure out the distal end of the insertion device; there would be no motivation or reason to modify the reference to extend the structure from a different location along the length of the insertion device.

Similarly, independent claim 9 as pending expressly requires tissue approximating means to be on the proximal side of the balloon. This compares to the Orban reference in a similar manner.

Independent claim 26 recites: “the first and second tissue approximating structure located on a proximal side of the drainage aperture.” This also compares to the Orban reference in a similar manner.

Overall, each of these independent claims distinguishes over the Orban structure by requiring tissue approximating structure to be located on a proximal side of a different structure of a catheter body, e.g., a balloon or a drainage aperture. That requirement further requires that the tissue approximating structure does not extend from the distal end of the catheter body, which is the only possible location for extending the Orban fastener structure.

In sum relative to the Orban reference, the rejection is based on a reading of Applicants’ claims as failing to distinguish over the Orban structure at figures 7 and 8. Because -- contrary to the rejection -- all of the pending the claims do distinguish from that structure, the rejection should be withdrawn.

Moreover, relative to the Salama reference, various features of the independent and dependent claims also differ. For example, the Salama reference fails to teach or suggest various features recited by the pending claims, and even teaches away from certain express features of the pending claims such as:

- i) tissue approximating structure on a proximal side of a balloon or drainage lumen, at a distal end of a catheter;
- ii) tissue approximating structure on a proximal side of a balloon, capable of contacting tissue selected from tissue of a bladder, tissue of a perineal wall, urethral tissue, and combinations of these;
- iii) tissue approximating structure comprising movable elongate structure selected from a tine, a probe, a prod, and a needle;
- iv) tissue approximating structure on a proximal side of a balloon that can be extended (and retracted);
- v) tissue approximating structure that can be extended and retracted through apertures in a catheter body; and
- vi) tissue approximating structure useful in combination with an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end.

In response to Applicant's assertion that Salama teaches away from features of the claims, the Advisory Action asserts that "one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references." To the contrary, references must be taken as a whole for what they teach as a whole, including critical differences between the claims and the references. An obviousness analysis must recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. Applicants have identified various distinctions between the features of the claims and features of the cited references, and those differences are to be considered in gauging inventiveness of the claims.

### **Conclusion**

In view of the present amendments and remarks, Applicants submit that the outstanding rejections have been either overcome or should otherwise be withdrawn. Reconsideration of the claims as amended, and allowance of the pending claims, are respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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